UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Bo Davis, MS, PM03

From: Dee Colby, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Entomologist

Date: 2016-December-22

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 389858
Decision no.: n/a
Submission no: n/a
Action code: n/a
Product Name: Whitmire PT 120 XLO Sumithrin Contact Insecticide
EPA Reg. No or File Symbol: 499-371
Formulation Type: aerosol
Ingredients statement from the label with PC codes included:
Phenothrin (1%) PC: 069005
Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m^2 or mg/cm^2 or mg/kg body weight as appropriate): Inject into crack & crevices with a 1 sec spray; depending on pest, apply at 1- 3 ft/sec; 1 sec/ft^2; 1-29 sec/1000 ft^3; 5-10 sec/3/ft^3

Use Patterns: In and around commercial and residential buildings: as a crack & crevice spray and fogger of voids, premise, volumetric treatment, carpet, drapes, furnishings, cabinets, baseboards, crack/crevice treatments, etc. for control of multiple arthropod species.

I. Action Requested: Efficacy review of submitted MRIDs supporting label claims for product reregistration (DP# 389858).

II. Background: Product specific data were called in for phenothrin to support the reregistration of the product.

III. MRID Summary:

46054701. Cardoza, R. and R. Kirkland. (2003) Evaluation of Cy-Kick CS Pressurized Crack & Crevice Residual, Cykick CS Controlled Release Cyfluthrin, formula 119-064 and formula 83-023 in the knockdown of the southern house mosquito.

(1) non-GLP

(2) Methods: This laboratory study was conducted to assess direct spray efficacy of experimental insecticides against the southern house mosquito, *Culex quinquefasciatus*, adults. Mosquitoes were from lab colonies; tests consisted of 4 reps of 10 mosquitoes each for insecticide treatments and UTC. Insecticides tested were not product specific: 1) Prescription Treatment Brand Cy-Kick CS Pressurized Crack & Crevice Residual 0.1 cyfluthrin aerosol formulation, 2) Prescription Treatment Brand Cy-Kick CS Controlled Release 6.0% cyfluthrin liquid formulation, 3) formula 119-064 aerosol consisting of 0.25% pyrethrum, 0.25% permethrin, and 2% PBO, and 4) formula 83-023 aerosol with 1% D-phenothrin, which corresponds to the PT-120 XLO product. Mosquitoes were held in screen-lidded containers (20.87 in^3) and sprayed with ~ 1g of formulation per replicate. Mortality was assessed at 30 sec, 1, 2, 3, 5, 10 and 15 minutes post treatment.

(3) Results: Each of the aerosol formulations killed 100% of the mosquitoes within 30 sec. The Cy-Kick liquid formulation achieved 95% mortality of mosquitoes within 5 min and 100% at 10 min post-treatment. No mortality occurred in controls.

(4) Conclusion: While this MRID is acceptable to support a direct spray kills claim for each of the experimental insecticides tested at ~ 1g of formulation in 20.87 in^3 against *Culex quinquefasciatus* adults, it is **unacceptable** to support a kills claim at the label rates for Whitmire PT 120 XLO Sumithrin Contact Insecticide. The tested rate of application, applied as 1 g/20.87 in^3, does not equate the volumetric treatment label rate for Whitmire PT 120 XLO Sumithrin Contact Insecticide for mosquitoes of 1-3 sec upward spray/1000 ft^3 to mimic a fogger. If a 1 sec spray is ~ 1 g of product, then the rate applied in the study would greatly exceed the label rate. Other label rates for mosquitoes include crack & crevice/void applications at 1 sec of spray, 3 ft/sec of spray, and 5-10 sec spray/3 ft^3, and outdoor ground applications at 1.5-2 sec of spray/1000 ft^2. Efficacy tests support a direct contact spray only.

Also, to obtain any mosquito claim acceptable data should be submitted on *Culex*, *Aedes*, and *Anopheles* mosquitoes. Testing of one of the following *Culex* species is preferred: *C. pipiens*, or *C. quinquefasciatus*, or *C. tarsalis*. Testing of one of the following *Aedes* species is preferred: *Ae. albopictus*, or *Ae. aegypti*. Testing of one of the following *Anopheles* species is preferred: *A. quadrimaculatus*, or *A. freeborni*, or *A. punctipennis*, or *A. gambiae*.

46054702. Cardoza, R. and R. Kirkland. (2003) Evaluation of Cy-Kick CS Pressurized Crack & Crevice Residual, Cykick CS Controlled Release Cyfluthrin, formula 119-064 and formula 83-023 in the knockdown of the bed bug.

(1) non-GLP

(2) Methods: This laboratory study was conducted to assess direct spray efficacy of experimental insecticides against the bed bug, *Cimex lectularius*, adults. Bed bugs were from a commercial insectary; tests consisted of 4 reps of 10 bed bugs each for insecticide treatments and UTC. Insecticides tested were not product specific: 1) Prescription Treatment Brand Cy-Kick CS Pressurized Crack & Crevice Residual 0.1 cyfluthrin aerosol formulation, 2) Prescription Treatment Brand Cy-Kick CS Controlled Release 6.0% cyfluthrin liquid formulation, 3) formula 119-064 aerosol consisting of 0.25% pyrethrum, 0.25% permethrin, and 2% PBO, and 4) formula 83-023 aerosol with 1% D-phenothrin, which corresponds to the PT-120 XLO product. Bed bugs were held in 32 oz deli cups and sprayed with ~ 1g of formulation per replicate, then immediately transferred to clean deli cups. Mortality was assessed at 30 sec, 1, 2, 3, 5, 10, 15 and 30 minutes post treatment.

(3) Results: Formula 119-064 aerosol killed 90% of bed bugs within 30 sec and 100% by 2 min post-treatment. Formula 83-023 killed 95% of bed bugs within 1 min and 100% by 3 min post-treatment. Prescription Treatment Brand Cy-Kick CS Pressurized Crack & Crevice Residual killed 97.5% of bed bugs within 10 min and 100% by 15 min post-treatment. Prescription Treatment Brand Cy-Kick CS Controlled Release killed 97.5% of bed bugs within 15 min and 100% by 30 min post-treatment. No mortality occurred in controls.

(4) Conclusion: This MRID is **partially acceptable** to support a direct spray kills claim for bed bugs for Whitmire PT 120 XLO Sumithrin Contact Insecticide. Label application instructions for Whitmire PT 120 XLO Sumithrin Contact Insecticide for bed bugs direct the user to "apply as a Crack & Crevice or spot treatment," but this study does not support residual DFU or claims as would be associated with these applications. In addition, for any bed bug claim, a pyrethroid resistant population or field-collected strain should be tested.

46495401. Cardoza, R. and R. Kirkland. (2003) Evaluation of Cy-Kick CS Pressurized Crack & Crevice Residual, Cykick CS Controlled Release Cyfluthrin, formula 119-064 and formula 83-023 in the knockdown of the bed bug.

This MRID is a duplicate of MRID 46054702 and should be removed from the data matrix.

48440204. Water, H. (2008) Laboratory bioassay to determine the efficacy of products against bed bug eggs, *Cimex lectularius*.

(1) non-GLP

(2) Methods: This laboratory study was conducted to assess efficacy of Crack and Crevice III (1% phenothrin) and Bedlam (0.4% phenothrin + 1.6% MGK-264) insecticides against the bed bug, *Cimex lectularius*, egg hatch rate and larval mortality. Tests consisted of 4 reps of 4.5 cm diameter bed bug egg clusters (17-51 eggs/batch) each for insecticide treatments and UTC. Batches of eggs, laid on filter paper, were contained in petri dishes. Filter paper were sprayed from a distance of ~ 18 inches using an aerosol spray apparatus delivering a 1 sec spray and then placed in petri dishes along with the batches of eggs. Numbers of bed bug nymphs were recorded daily for 18 d; exposure was continuous. Eggs were also assessed as appearing: normal, dead, hatched but incomplete eclosion, hatched but nymph dead on or off filter paper, and hatched with normal nymph. Nymphs were removed after each assessment. Cumulative percentage of nymphs at each assessment per treatment were analyzed using a Mann-Whitney non parametric test.

(3) Results: Untreated controls averaged 98.3% egg hatch. Crack & Crevice III treated eggs had 63.3 % of eggs die by 18 d post treatment and 41.7% died for Bedlam. Of the eggs that hatched, 33.7% of Crack & Crevice III and 53.3% of Bedlam treated eggs produced nymphs that died by 18 d post treatment; ~ 3% of Crack & Crevice III and 5% of Bedlam treated eggs produced normal nymphs by 18 d.

(4) Conclusion: This MRID is **unacceptable** to support ovicidal claims for bed bug eggs for both insecticides tested at ~ 1 sec of spray on a filter paper surface. Percentages of egg mortality and failure to molt beyond 1st instar nymph were both below acceptable levels (i.e., 90%). The rate of application of Crack and Crevice III, as applied, may or may not equate to the label rate for Whitmire PT 120 XLO Sumithrin Contact Insecticide for bed bugs because there are no label rates listed. Label Application Instructions for Whitmire PT 120 XLO Sumithrin Contact Insecticide direct the user to "apply as a Crack & Crevice or spot treatment". This study does not support residual DFU or claims as would be associated with crack and crevice applications, but would support "spot treatments" provided acceptable data were submitted. In addition, for any bed bug claim, a pyrethroid resistant population or field-collected strain should be tested.

48440202. Robinson, W. and J. Mollet (1993) Chemical control of the house dust mite *Dermatophagoides pteronyssinus*, using an aerosol application of 1% Sumithrin.

(1) non-GLP

(2) Methods: This was a semi-field test to evaluate product specific efficacy of Whitmire PT 120 XLO Sumithrin Contact Insecticide (EPA Reg. No. 499-371) against house dust mites on couch cushions. House dust mite populations on 6 couch cushions were determined by vacuuming the cushion for 2 min each per square meter of cushion. The number of mites, pretreatment, was calculated based on the number of living mites per 1 g of dust or in 0.25 m^2. Cushions were returned to couches for 7 d, after which they were treated with Whitmire PT 120 XLO Sumithrin Contact Insecticide for 3 sec/0.5 m^2 (label rate equivalent). Four cushions were treated the insecticide and 3 cushions served as UTC. Mite populations were measured at 24 h and 3 d post treatment. The percentage reduction in dust mite populations was determined by comparing the number of living mites pretreatment to the number of mites after treatment on 0.25 m^2 of cushion.

(3) Results: Data were pooled across treated cushions to show 84.5% reduction in dust mites per 0.25 m^2, or 1 g of dust, at 24 h and 3 d post treatment. No raw data nor numbers of mites observed on control cushions was provided.

(4) Conclusion: This MRID is **unacceptable** to support a kills claim for Whitmire PT 120 XLO Sumithrin Contact Insecticide spray of fabric against dust mites. While data indicated a reduction in dust mites on treated couch cushions for 1 – 3 d post treatment, the percentage reduction did not reach an acceptable level of control (i.e., 90%) during the study. Also, data from controls was not presented and would need to be included with acceptable data.

48440203. Todd, R. (1983) Efficacy of Grow™ Flea and Tick Spray for dogs against adult human body lice and cat flea larvae.

(1) non-GLP

(2) Conclusion: This study is not product specific and not relevant to support efficacy of Whitmire PT 120 XLO Sumithrin Contact Insecticide. The product that was tested, Grow™ Flea and Tick Spray (listed as EPA Reg. No. 44795-2), contains tetramethrin 0.05% in addition to phenothrin 0.1% and was cancelled in 1989.

47000402. Cardoza, R. and R. Kirkland (2003) Evaluation of formula 119-064 and formula 83-023 in the control of the German cockroach, American cockroach, house fly, stable fly, cellar spider and honey bee.

(1) non-GLP

(2) Methods: This laboratory study was conducted to assess direct spray efficacy of experimental aerosol insecticides against the following pests: German cockroach, *Blatella germanica*; American cockroach, *Periplaneta americana*; house fly, *Musca domestica*; stable fly, *Stomoxys calcitrans*; cellar spider, *Pholcus phalangiodes*; and honey bee, *Apis mellifera*. Cockroaches and honey bees were from laboratory colonies, cellar spiders were field collected, and flies were purchased from a commercial insectary. Experimental insecticides were not product specific: 1) formula 119-064 aerosol consisted of 0.25% pyrethrum, 0.25% permethrin and 2% PBO, and 2) formula 83-023 aerosol with 1% D-phenothrin corresponds to the PT-120 XLO product. Four replicates of 10 individuals each (n = 40) for the German roach, house fly, and stable fly; 4 replicates of 5 individuals each (n = 20) for the American roach and honey bee; 10 replicates of 1

individual each (n = 10) for the cellar spider were held in 32 oz deli cups (if crawling) or screen-lidded containers (if flying) and sprayed with ~ 1g of formulation per replicate, then immediately transferred to clean deli cups (if crawling). Flying insects were not removed from treated containers. An equal number of individuals and reps per species served as UTC. Mortality was recorded at 0.5, 1, 2, 3, 5, 10, 15, 30 and 60 minutes after application.

(3) Results:

TRT	Active Ingredients	Mean time (minutes) to ≥90% Mortality					
		GCR	***ACR***	***HF***	***SF***	***CS***	***HB***
83-023	1.0% d-Phenothrin	15	10	1	0.5	10	1
119-064	0.25% Pyrethrum 0.25% Permethrin 2.00% PBO	10	10	2	1	10	1

Table. Treatments applied and mortality observed as a result of direct contact spray of insects. (***GCR*** = German cockroach; ***ACR*** = American cockroach; ***HF*** = house fly; ***SF*** = stable fly; ***CS*** = cellar spider; ***HB*** = honey bee). No mortality occurred in controls.

(4) Conclusion: This MRID is **partially acceptable** to support a direct spray kills claim for each of the experimental insecticides tested against German cockroaches and spiders (excluding black widow and brown recluse) and only as a volumetric treatment "contacting as many insects as possible". Label application instructions for Whitmire PT 120 XLO Sumithrin Contact Insecticide direct the user to inject into cracks and crevices and apply as a volumetric treatment at the rate of 20 sec/1000 ft^3 when treating for roaches and spiders. This study does not support residual DFU or claims as would be associated with crack and crevice applications.

For house flies and stable flies (i.e., flying insects), the rate of application of the experimental formulation applied as 1 g in the volume of a 32 oz cup, does not equate to the label rate for Whitmire PT 120 XLO Sumithrin Contact Insecticide for "Flying Insects" of 1-3 sec upward spray/1000 ft^3 to mimic a fogger. If a 1 sec spray is ~ 1 g of product, then the rate applied in the 32 oz cup greatly exceeds the label rate.

Lastly, the number of individuals for the American cockroach and honey bees was unacceptable low. Tests should be conducted with five replicates of at least 10 individuals. Departures from this should be justified in the submitted study.

IV. EXECUTIVE DATA SUMMARY:

(A) Acceptable data was provided for direct spray kills claims for German cockroaches and spiders (excluding black widow and brown recluse). A general 'cockroach' label claim should include acceptable data for the German cockroach (*Blattella germanica*) and the American cockroach (*Periplaneta americana*). Without adequate data to support product performance, the following insect groups should be removed from the label: American cockroach, bed bugs, bees and hives, centipedes, cluster flies, cockroaches/roaches, fleas, horn flies, house dust mites, biting gnats, house flies, lice, mosquitoes, stable flies, ticks, and wasps/nests. In addition:

1) For any bed bug claim, a pyrethroid resistant population or field-collected strain should be tested.

2) We prefer that testing of centipedes includes one of the following species: house centipede (*Scutigera coleoptrata*) or Florida blue centipede (*Hemiscolopendra marginata*).

3) For biting gnats/midges (punkie, granny nipper, no-see-um), one (*Culicoides* sp.) and one Black gnat (*Leptoconops* sp.) should be tested to support efficacy against biting gnats. Non-biting gnats may be listed on a label without a review of data, but should be designated as "non-biting".

4) Ants (excluding carpenter, harvester, pharaoh, and fire ants) may be listed on a label without a review of data, but must be listed with the exclusions.

5) For any tick claim, data should be submitted for the following three species: *Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick) or *Rhipicephalus sanguineus* (brown dog tick), and *Ixodes scapularis* (black-legged tick).

6) A general fly claim should be supported by acceptable efficacy data for the following public health pest species: house fly (*Musca domestica*), flesh fly (Sarcophagidae) or blow fly (*Phaenicia sericata*), biting midge (*Culicoides* spp.), stable fly (*Stomoxys calcitrans*) and black fly (*Simulium* spp. or *Prosiumulium* spp.).

7) To obtain any mosquito claim acceptable data should be submitted on *Culex*, *Aedes*, and *Anopheles* mosquitoes. Testing of one of the following *Culex* species is preferred: *C. pipiens*, or *C. quinquefasciatus*, or *C. tarsalis*. Testing of one of the following *Aedes* species is preferred: *Ae. albopictus*, or *Ae. aegypti*. Testing of one of the following *Anopheles* species is preferred: *A. quadrimaculatus*, or *A. freeborni*, or *A. punctipennis*, or *A. gambiae*.

Other reasons that the data was determined to be unacceptable included:

1) Treatment application rates and label use rates were not equivalent.

2) Testing for residual claims, such as crack and crevice, was not included in submitted studies but does appear in DFU on the product's label. Acceptable data would need to be submitted to support arthropods and claims requiring DFU with residual application. For an indoor residual claim, both a porous (e.g., unpainted, unfinished plywood) and nonporous surface (e.g., linoleum or glazed tile) should be tested. If mattresses, fabric and/or carpet are included as a labeled site, efficacy data using cotton sheeting, mattress ticking, and/or carpet should also be provided. The Agency prefers that surfaces be aged under environmental conditions which simulate proposed use conditions.

3) Numbers of individuals tested may have been unacceptably low. Tests should be conducted with five replicates of at least 10 individuals. The design should be balanced with an equal number of treated and untreated replicates. Departures from this should be justified in the submitted study.

I. LABEL RECOMMENDATIONS:

(1) Directions for use:

- Remove directions for use for American cockroach, bed bugs, bees/Africanized bees/nests/comb, centipedes, cluster flies, cockroaches/roaches, fleas, flies, horn flies, house dust mites, biting gnats, house flies, lice/lice eggs, mosquitoes, stable flies, ticks, and wasps/nests.
- Directions for German cockroaches and spiders (excluding black widow and brown recluse) should specify direct spray of German cockroaches and spiders (excluding black widow and brown recluse) during volumetric treatment; remove directions for crack and crevice treatment of hiding places for these arthropods
- Gnats should be specified as non-biting gnats
- Ants should be specified as ants (excluding carpenter, harvester, pharaoh, and fire ants)

(2) The following marketing claims are acceptable:

- Kills claims for German cockroaches and spiders (excluding black widow and brown recluse) by contact only
- Kills claims and residual DFU for non-public health pests
- Kills claims for ants (excluding carpenter, harvester, pharaoh, and fire ants)

(3) The following marketing claims are unacceptable:

- Claims suggesting efficacy against American cockroach, bed bugs, bees/Africanized bees/nests/comb, centipedes, cluster flies, cockroaches/roaches, fleas, flies, horn flies, house dust mites, biting gnats, house flies, lice/lice eggs, mosquitoes, stable flies, ticks, and wasps/nests; carpenter, harvester, pharaoh and fire ants; black widow and brown recluse spiders
- Residual efficacy claims and DFU (i.e., crack and crevice) for species listed above, as well as, bed bugs, German cockroaches, and spiders (excluding black widow and brown recluse)

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: **46054701, 46495401, 48440202, 48440203 and 48440204**